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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,356

12/11/2006

Richard R. Bott

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DINSMORE & SHOHL LLP
FIFTH THIRD CENTER, ONE SOUTH MAIN STREET
SUITE 1300
DAYTON, OH 45402-2023

EXAMINER

PARK, HAEJIN S

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/576,356	Applicant(s) BOTT ET AL.
	Examiner H. SARAH PARK	Art Unit 1611

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 July 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 72 and 74-91.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SHARMILA G. LANDAU/ Supervisory Patent Examiner, Art Unit 1611	/HSP/ Examiner, Art Unit 1611
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Continuation of 11. does NOT place the application in condition for allowance because: SApplicant's arguments have been fully considered but have not been found persuasive.

Applicant first contends that Kosal (i) does not teach controlled release properties of its pressure sensitive adhesive composition, and (ii) only mentions using an active agent in conjunction with the pressure sensitive adhesive (PSA) in the context of a covering or dressing to secure contact of an active against the skin (Remarks at 6).

This argument is unpersuasive because Kosal nowhere limits the disclosure on holding a fungicide to skin to those embodiments where the PSA acts solely as a covering or dressing. Furthermore Kosal states just prior to discussing patches and fungicides that its PSA can be used in mascaras and sunscreens (col.5 l.22) which products are not provided in coverings or dressings.

Applicant next argues that Bott et al. teaches placing an active agent in the discontinuous phase in a water-in-oil (WO) emulsion (in other words active is in the water phase), and "[t]hus, the Bott composition is not only very different from the presently-claimed composition, it differs significantly from Kosal. Unlike Kosal, Bott teaches..." (Remarks at 6-7).

This argument is unpersuasive because Applicant expounds at length the teachings of Bott et al., but fails to specifically distinguish them from the teachings of Kosal. Further, Applicant references its "previous response", concerning which Applicant is directed to note examiner's previous response in the final rejection at para.9 et seq. Also it is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant next argues that there is a material difference between locating an active in an OW emulsion versus simply holding an active agent against a patient's skin as taught in Kosal, and Kosal does not address any problem relating to controlled release of an active from an adhesive composition.

The arguments are unpersuasive because as noted in the final rejection Bott et al. teaches sustained release topical preparations and the rejection was based on both Bott et al. and Kosal.

Applicant specifically argues that the assertion in the Action that skilled persons would appreciate that Kosal's use of a thickening agent modifies release of the active agent is speculation, not evidence.

This argument misses the point. While Kosal may not teach this explicitly, as stated, the skilled person would appreciate that thickeners and carriers can be used to modify release of actives, for example by modifying the viscosity of the emulsion and through which the active agent must diffuse. The prior art is assessed from the view of a person skilled in the relevant art, not an uninformed layman.

Applicant next alleges factual and legal error in the statement that "absent evidence, it is not seen that the composition of Kosal et al. prepared by phase inverting the composition of Bott et al. would result in a different mechanism, not rate, of release control" because "it is the Office's legal burden to establish evidence that supports conclusion of obviousness".

This argument is unpersuasive because the MPEP is silent as to the Office's burden to provide "evidence" that supports obviousness. What the MPEP requires is: "[t]he examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness," depending on which Applicant may present evidence of nonobviousness to overcome the prima facie case. MPEP 2142. Applicant is suggested to consult the prior Office action concerning the factual support for the prima facie conclusion of obviousness. Furthermore concerning the allegedly limited mechanisms of release of the active agent as creation of pores, crevices, cracks, or fissures within the silicone matrix, note that silicone may undergo such changes whether in an OW or WO emulsion.

Applicant next contends that no motivation has been established, especially because "Kosal is directed to a pressure sensitive adhesive and Bott, primarily, is not".

This argument is unpersuasive because as noted above Kosal is not directed to a pressure sensitive adhesive in that capacity alone, but also to formulations comprising the PSAs that are directly applied on the skin such as mascaras, sunscreens, and fungicides.

Applicant next argues concerning claims 87-88 that no motivation was provided to combine Woodard et al. with Kosal and Bott et al.

This argument is unpersuasive, since as noted in the final rejection Woodard et al. is an evidentiary reference reflecting on the state of the prior art on transdermal patch layers as would have been known to one of ordinary skill in the art.

Applicant finally argues concerning claim 89 that no prior art reference teaches a controlled release layer free of water in an embodiment comprising an OW emulsion.

This argument is unpersuasive in view of the final rejection of this claim based on Kosal in combination with Bott et al. It is again noted that one cannot show nonobviousness by attacking references individually where the rejection is based on a combination of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

For these and other reasons set forth in the final rejection, the rejections are maintained.